REMARKS

I. Status of the Application

This paper responds to a non-final office action mailed February 27, 2007. The application was originally filed with claims 1-22. In a response to a restriction requirement, Applicant elected invention Group 1, claims 1-9 and 16-22. This paper amends claim 1 and 3, withdraws claims 10-15, cancels claims 19-22, and further provides remarks to overcome the Office rejection. Claim 3 was amended because of a typographical error. Accordingly, claims 1-9 and 16-18 are currently under consideration in this application.

II. Time for Reply

This paper responds to a Non-final Office Action which was mailed on February 27, 2007. The Non-final Office Action set a shortened statutory period for reply of three months from the mailing date, making the response due on or before Sunday, May 27, 2007. Applicant is timely filing this paper on Wednesday, May 23, 2007, which is within the three-month period for reply.

III Rejection of Claims 1-9 and 16-18 under 35 U.S.C. § 112, ¶1

The Office action rejected claims 1-9 and 16-18 under 35 U.S.C. §112, ¶1 for failing to comply with the enablement requirement. According to the Office action, "the specification does not provide sufficient guidance and information to one of skilled in the art so that they can practice the prevention of hot flashes", and that ... "undue experimentation is necessary to determine screening and testing protocols to demonstrate the efficacy of the presently claimed invention." Applicant has amended Claim 1 by deleting "and prevention" which renders the rejection moot. Therefore, Applicant respectfully requests withdrawal of the rejection as applied to the pending claims.

Moreover, as set out by the Federal Circuit, a "considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which

experimentation should proceed." *In re Wands*, 8 U.S.P.Q.2d 1400, 1404 (Fed. Cir. 1988). Those of skill in the art can carry out the instant invention as described in the specification on pages 5 (line 6) through 6 (line 12). For example, the specification describes hormonal imbalances in female patients caused by menopause, radiation therapy, or certain medications. Further, a skilled practitioner would be expected to determine the appropriate level of dosing to alleviate the symptoms of hot flash. Therefore, the specification enables one of skill in the art to treat hot flash, in a patient in need of such treatment, by administering a therapeutically-effective amount of reboxetine as described in claim 1. Thus, Applicant submits that one of ordinary skill in the art can ascertain the metes and bounds of the claimed invention and therefore respectfully requests withdrawal of the rejection.

IV. Rejection of Claims 1-9 and 16-18 Under 35 U.S.C. §103(a)

The Office action has rejected claims 1-9 and 16-18 under 35 U.S.C. §103(a) as being unpatentable over Script in view of Holm and Spencer (hereinafter, "Holm"). Applicant submits that the claims of the present application are patentable over Script in view of Holm and further requests that Examiner reconsider the claims as amended.

Scrip describes the use of low doses of either a serotonin reuptake inhibitor (SRI) (e.g. fluoxetine and paroxetine) or a serotonin and norepinephrine reuptake inhibitor (SNRI) (e.g. venlafaxine) to provide relief of hot flashes in women with a history of breast cancer or for men with a history of prostate cancer, and not the general use of anti-depressants to treat hot flashes. The SRI's are adrenergic compounds that specifically inhibit the reuptake of serotonin from the neuronal synapse. The SNRI's are adrenergic compounds that inhibit the reuptake of both serotonin and norepinephrine from the neuronal synapse. Therefore, Scrip implies that a serotonin reuptake inhibitor or a combined serotonin-noreinephrine reuptake inhibitor is required for the treatment of hot flashes, suggesting that modulation of serotonin is required to treat hot flash. Since reboxetine and S,S-reboxetine are selective norepinephrine reuptake inhibitors with

minimal effects on serotonin, one skilled in the art would not anticipate that reboxetine or S,S-reboxetine would be useful for the treatment of hot flash.

Further, Holm describes reboxetine as a selective noradrenaline reuptake inhibitor with similar efficacy to fluoxetine in treating depression. However, the third sentence of the pharmacodynamic properties section of the reference summary states "Reboxetine does not affect dopamine or serotonin reuptake and it has low *in vivo* and *in vitro* affinity for adrenergic, muscarinic, cholinergic, histaminergic, dopaminergic, and serotonergic receptors." As such, Holm teaches away from using reboxetine to inhibit serotonin reuptake. Therefore, it would not be obvious for a skilled artisan to treat a patient suffering from hot flash with reboxetine, as the compound does not modulate serotonin uptake and it has a low affinity for adrenergic receptors. Therefore, based on the prior arguments, Applicant respectfully requests that the rejection be withdrawn and the claims, as amended, be allowed to issue.

V. Conclusion

Based on the foregoing, Applicant respectfully submits that the present application is in condition for allowance. Applicant believes that no fees are due with respect to the filing of this paper. However, if Applicant has overlooked any fees required in connection with the filing of this paper, please charge deposit account number 16-1445.

Respectfully submitted,

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